11-Aug-00

EQUI AID PRODUCTS, INC.

Dr. Lonnie Luther
FDA, CVM HFC 102 Room 387
Generic Drug Branch
7500 Standish Place
Rockville, MD 20855

Dear Dr. Luther;

I have enclosed a Suitability Petition submission in reference to JINAD 10-664, ivermectin paste for horses. The reference (pioneer) product is Eqvalan® Paste for Horses; NADA 134-314 sponsored by Merial Ltd.

This submission is based on the Pre-ANADA Activities, ANADA Suitability Petition section in the second policy letter on the implementation of the Generic Animal Drug and Patent Term Restoration Act dated June 7, 1989.
Specifically the Pre-ANADA Activities, ANADA Suitability Petition section in the second policy letter states:

> "The filing of a Suitability Petition provides a means by which a firm may request permission to file an ANADA for a product which differs from the approved pioneer product.
> The specific variances under the Act for which a Suitability Petition may be submitted are as follows:
> 1. Change of one ingredient in a combination product or premix
> 2. Change of a dosage form
> 3. Change of a strength of an ingredient
> 4. Change in route of administration
> 5. Change in use with other animal drugs in animal feed."

Equi Aid is requesting permission to file an ANADA that differs from the pioneer in that the pioneer is a paste oral dosage form containing 1.87% ivermectin and the proposed product would be a chewable containing 22.7 mg ivermectin per chewable. Thus the proposed product would differ in dosage form, and strength.

The proposed generic product would contain animal feeds as inactive ingredients and would be administered via hand feeding, top-dress on feed or by mixing in the horses grain ration.

Sincerely;

Peter R. Miller DVM MS

RECEIVED
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By

00P-1486

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623-492-9190
1517 West Knudsen Drive
Phoenix, Arizona 85027
623-492-9385 (FAX)

Equi Aid Suitability Petition
Ivermectin Chewable Wormer for Horses
JINAD 10-664
11-Aug-00

Table of Contents

Equi Aid Suitability Petition
Ivermectin Chewable Wormer for Horses
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1. Identification of Petitioner and Statutory Citation

Petitioner
Equi Aid Products, Inc.
1517 W. Knudsen Drive
Phoenix AZ 85027

Statutory Citation
Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

2. Action Requested

Equi Aid Products, Inc. is petitioning the Commissioner to permit filing of an ANADA for a generic oral ivermectin for horses which differs from the approved pioneer product (Eqvalan®, NADA 134-314; Paste) in dosage form and strength of an active ingredient.

3. Statement of Grounds

(a) Identification of a single listed drug which is the basis of the petition
The reference (pioneer) product forming the basis for this petition is Eqvalan® Paste; NADA 134-314 sponsored by Merial Ltd.

i) Description of the pioneer product Eqvalan® (Paste for Horses)

134-314 Eqvalan Paste

Tradename:	Eqvalan Paste
NADA Number:	134-314
Sponsor:	Merck Research Laboratories
Ingredients:	Ivermectin
Species:	Equine, Horses not for meat production
Rx or OTC:	OTC
Route of Administration:	Per Os
Drug Forms:	Oral Paste
CFR Information:	520.1192 Ivermectin Paste.
Specifications.	Paste contains 1.87 percent ivermectin.

Conditions of use

Amount.
200 micrograms per kilogram of body weight as a single dose.
Indications for use.
It is used in horses for the treatment and control of
large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus endentatus*), (adult) (*Triodontophorus* spp.);
small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (*Cyathostomum* spp. *Cylicocyclus* spp.,

Cylicodontophorus spp. *Cylicostephanus* spp.);
pinworms (adult and fourth stage larvae) (*Oxyuris equi*);
ascarids (third - and fourth-stage larvae and adults) (*Parascaris equorum*);
hairworms (adult) (*Trichostongylus axei*);
large mouth stomach worms (adult) (*Habronema muscae*);
stomach bots (oral and gastric stages) (*Gastrophilus* spp.);
lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*);
intestinal threadworms (adults) (*Strongyloides westeri*);
summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and
dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).
Limitations.
For oral use only.
Do not use in horses intended for food purposes.
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

ii) Description of the proposed product Ivermectin Chewable Wormer for Horses

JINAD 10-664 Ivermectin Chewable Wormer for Horses

Tradename:	**(Not yet established)**
Ref Number:	JINAD 10-664
Sponsor:	Equi Aid Products, Inc.
Ingredients:	Ivermectin
Species:	Equine, Horses not for meat production
Rx or OTC:	OTC
Route of Administration:	Per Os
Drug Forms:	chewable
Proposed CFR Information:	520.1193 Ivermectin Tablets and Chewables.
Specifications:	Contains 22.7 mg ivermectin per chewable.

Conditions of use:
It is used as follows;....
Horses
Amount.
200 micrograms per kilogram of body weight as a single treatment.
Indications for use.
It is used in horses for the treatment and control of
large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus endentatus*), (adult);
small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (*Cyathostomum* spp. *Cylicocyclus* spp., *Cylicodontophorus* spp. *Cylicostephanus* spp.) (*Triodontophorus* spp.[1]);
pinworms (adult and fourth stage larvae) (*Oxyuris equi*);
ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*);
hairworms (adult) (*Trichostongylus axei*);

[1] *Triodontophorus* spp is not generally considered a large strongyle. Currently, it is typically classified as a small strongyle.

large mouth stomach worms (adult) (*Habronema muscae*);
stomach bots (oral and gastric stages) (*Gastrophilus* spp.);
lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*);
intestinal threadworms (adults) (*Strongyloides westeri*);
summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and
dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).
Limitations.
For oral use only.
Do not use in horses intended for food purposes.
Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b) Proposed Changes

i) Dosage Form

- **Pioneer**
  The pioneer product is an oral dosage form (Paste) New Animal Drug (CFR Reference: 21 CFR 520.1192).
- **Generic**
  The proposed generic product is an oral dosage form (chewable) New Animal Drug (CFR Reference: 21 CFR 520.1193).

ii) Active Ingredients

Equi Aid is not proposing changes in the active ingredient.

iii) Strength

- **Pioneer**
  The pioneer product contains ivermectin at 1.87% ivermectin.
- **Generic**
  The proposed generic product would contain 22.7 mg ivermectin per chewable.

iv) Route of administration

- **Pioneer**
  The pioneer product is administered orally.
  Oral administration is via a paste syringe
- **Generic**
  The proposed generic product is administered orally.
  Oral administration is via hand-feeding, top-dressing on the horse's grain ration or mixing in the horse's grain ration.

(c) Justification for the proposed variances

i) General

Providing a palatable feed-based product as proposed would be beneficial in regard to both safety and efficacy because feeding the product would be expected to reduce difficulty of administration and possible rejection of the dose.
The change in strength is necessitated by the change in dosage form.

ii) Palatable Medications are a common means of drug delivery.

The use of palatable products as a means of drug delivery, including anthelmintic drugs, is well established. Other suitability petitions have been approved which allow for changing to a palatable "top-dress" or "mix-with-feed" type product (Petition 89P0509 and 96P0438).

iii) Change in strength

The proposed strength (22.7 mg/chewable) is appropriate to deliver a 200 ug ivermectin per kg body weight dose. (one chewable per 250 pounds of body weight; five chewables per 1250 lb horse).

The Pioneer paste is 1.87% ivermectin and has a net weight of 6.08 g. A 1250 pound horse weighs approximately 567 kg and should receive the entire net contents of the tube 6.08 g paste or approximately 113.7 mg ivermectin. This amounts to the labeled dose of 200 ug/kg body weight.

The proposed packet of five chewables would contain 22.7 mg ivermectin per chewable. A 1250 pound horse weighs approximately 567 kg and should receive all five of the chewables resulting in 113.5 mg ivermectin. This amounts to the labeled dose of 200 ug/kg body weight.

iv) Change in route of administration

- **Both products would be administered per os (by mouth)**

Pioneer Label Dosage and Administration: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight. (1) While holding the plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a ¼ turn to the right. (3) Make sure that the horse's mouth contains no feed. (5) insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing the paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

Proposed Generic Label Dosage and Administration: This package contains 5 chewables sufficient to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each chewable contains enough ivermectin to treat 250 lb body weight. Administer by hand feeding, as a top-dress on the horse's grain ration or mixed in the horse's grain ration.

4. Additional Essential Elements of a Petition

The Pre-ANADA Activities, ANADA Suitability Petition section in the second policy letter on the implementation of the Generic Animal Drug and Patent Term Restoration Act dated June 7, 1989 under "Additional essential elements of a petition" lists two items:

1) identification of a single listed drug which is the basis of the petition (which is addressed above) and

2) pioneer and proposed product labeling with differences noted and explained.

(a) Comparison of Pioneer and Proposed Product Labels

i) Immediate Closure Label

The pioneer's immediate closure is a syringe.

The pioneer's immediate closure label consists of an adhesive label wrapped around the syringe barrel.
The proposed generic product's immediate container label would be an integral part of the package and could be printed front and back.

- **For Use in Horses only**
  Appears at the very top of the pioneer label prior to the product name.
  Appears immediately after the product name on the proposed generic label.
- **PRODUCT NAME**
  Is prominent and appears near the top of the pioneer label and the proposed generic label.
- **Active Ingredient, Dosage Form and Strength**
  The text "(ivermectin) Paste 1.87%" appears on the pioneer label immediately following the pioneer name.
  On the proposed generic label the product name would be descriptive of the dosage form (i.e. chewable) or the dosage form would described immediately following the name. The active ingredient and the strength (ivermectin 22.7 mg/chewable) would appear on the proposed generic label immediately following the proposed generic name.
- **Anthelmintic and Boticide**
  The words "Anthelmintic and Boticide" appear on both the pioneer and proposed generic label after the active ingredient, dosage form and strength.
- **Abbreviated Indications**
  Both the pioneer and proposed product display indications that are abbreviated in that only the common names of the parasites are listed. The pioneer label omits lungworms, intestinal thread worms and summer sores from the abbreviated indications on the immediate closure. The proposed generic label would include the lungworms, intestinal thread worms and summer sores in the abbreviated indications. Both labels refer the user to the carton or attached labeling for complete indications. Both labels instruct the user to consult their veterinarian for assistance in the diagnosis, treatment and control of parasitism.
- **Warning and Caution Statements**
  Both immediate container labels have the same text for the warning and caution statements.
- **Size / Amount**
  Both the pioneer and proposed products list the container size/amount on the bottom of the label. The pioneer product (syringe) has a net weight of 0.21 OZ (6.08 g). The proposed product would indicate 5 chewables per package).
- **Lot Expiration Date and Name of Sponsor**
  Both the pioneer and proposed products show the lot number, expiration date and sponsor name on the bottom of the immediate container label. The proposed product would also have a UPC code on the immediate container.

- **Additional Label information**
  The package would have the product name, dosage form, active ingredient, strength, "Anthelmintic and Boticide", "For Oral Use in Horses Only", the size/amount and the sponsor name on the inside or back of the package closure. This information is the same as on the other side of the immediate closure as described above.
  The text "removes worms and bots with a single dose" is the same text as appears on the front of the pioneer secondary label.
  The pioneer administration labeling on the immediate closure consists of the syringe plunger being labeled in 250 lb increments up to 1250 pounds. This is similar to the dosing instructions described above (Contents will treat up to 1250 lb body weight", "One chewable per 250 pounds body weight") for the proposed generic product.

ii) Secondary container label or package insert

The secondary container for the pioneer is a clear plastic sleeve.
The secondary container label for the pioneer is a folded adhesive label attached to the sleeve.
The secondary closure for the proposed generic product is a box.
The secondary closure label for the proposed generic product is printed on the box.

- **Name, Active Ingredient, Dosage Form, Strength, "Anthelmintic Boticide" and "For Oral Use in Horses Only".**
  These items are the same as described for the immediate closure except for the "For Oral Use in Horses Only" text on the pioneer label appears further down the label.

- **"Removes worms and bots with a single dose" and "Contents will treat up to 1250 lb body weight.".**
  This text appears below the "Anthelmintic and Boticide" text on both the pioneer and generic labels. The proposed generic label adds the text "One chewable for each 250 lb body weight".

- **Indications**
  The indications are the same for the pioneer and proposed products.
  NOTE: Recently the *Triodontophorus* spp. have more commonly been included with the small strongyles as opposed to large strongyles as was done in the past. Therefore, the *Triodontophorus* spp. appears under the small strongyle heading on the generic label instead of the large strongyle heading.

- **Dosage and Administration**
  The proposed changes in the Dosage and Administration label text are addressed in the proposed changes above. See "Change in route of administration" above.

- **Parasite Control Program and Product Advantages, Safety, Warning, Caution and Note to User**
  The text of the pioneer and generic labels are the same for the Parasite Control Program, Product Advantages, Safety, Warning, Caution and Note to user sections.[2]

- **Net Weight/Amount, Trade Mark, Patent, Sponsor name**
  Both labels have net weight/amount and sponsor name near the end of the label. The pioneer label has patent and trade mark information that does not apply to the generic product. The proposed generic label would include lot number, expiration date and UPC code.

5. Environmental Impact

Equi Aid Products, Inc. requests, under 21 CFR 25.30 (h) categorical exclusion from the requirement for an environmental assessment. To the best of my knowledge no extraordinary circumstances exist that may affect the human environment.

6. Economic Impact

An "Economic Impact" section has not been requested. Equi Aid Products, Inc. will provide an "Economic Impact" statement upon the Commissioner's request.

7. Certification

I, Peter R. Miller DVM, MS, acting as Equi Aid's representative, have included all information known to me which is unfavorable to this petition.

Peter R. Miller DVM, MS
Equi Aid Products, Inc.
1517 W. Knudsen Dr.
Phoenix, AZ 85027
(623) 587 6082.

Peter R. Miller DVM MS 11-Aug-00

[2] The name of the generic product appears in place of the pioneer product name. On the generic label the generic product name or a product description (chewable) is used in place of the term "paste".

Product 25874 For Oral Use in Horses Only

Eqvalan®

(Ivermectin) Paste 1.87%

Anthelmintic and Boticide

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms, Bots. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

NET WT 0.21 OZ (6.08 g) Made in U.S.A.

WARNING: Do not use in horses intended for food purposes.

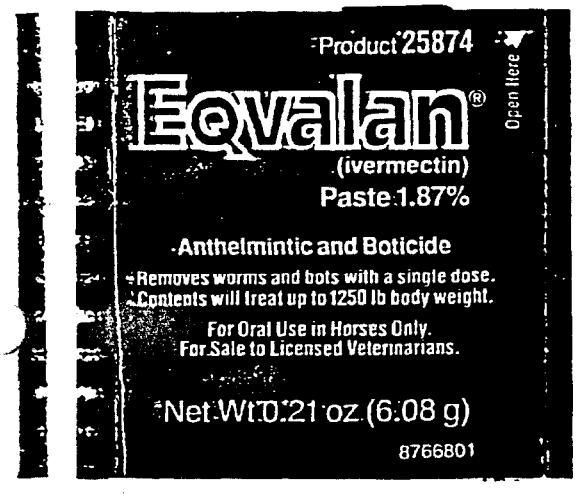
CAUTION: Refrain from smoking or eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children.

Lot No & Exp Date ▶ HBK056 10-2001

MERCK AgVet Division

8610304 Merck & Co., Inc. Rahway, New Jersey 07065-0912, U.S.A.

Label on syringe of Pioneer product



INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN® (ivermectin) Paste provides effective control of the following parasites in horses. **Large Strongyles** (adults) — *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp; **Small Strongyles** including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) — *Cyathostomum* spp, *Cylicocyclus* spp, *Cylicostephanus* spp, *Cylicodontophorus* spp; **Pinworms** (adults and fourth-stage larvae) — *Oxyuris equi*; **Ascarids** (adults and third- and fourth-stage larvae) — *Parascaris equorum*; **Hairworms** (adults) — *Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) — *Habronema muscae*; **Bots** (oral and gastric stages) — *Gastrophilus* spp; **Lungworms** (adults and fourth-stage larvae) — *Dictyocaulus arnfieldi*; **Intestinal Threadworms** (adults) — *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

1

DOSAGE AND ADMINISTRATION: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

2

(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe. (5) Insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares,

3

foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. EQVALAN® (ivermectin) Paste effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES: Broad-spectrum Control —EQVALAN Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. EQVALAN Paste is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate. ***Safety*** – EQVALAN Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

WARNING: Do not use in horses intended for food purposes.

4

CAUTION: EQVALAN (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children.

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp microfilariae). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive

5

tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

EACH SYRINGE CONTAINS 0.21 OZ (6.08 g) IVERMECTIN PASTE

EQVALAN REG TM MERCK & CO., INC.

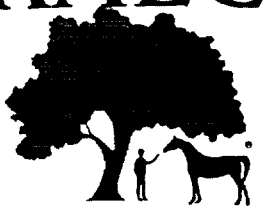
U.S. Pat. 4,199,569 Made in U.S.A.

MERCK AgVet Division

Merck & Co. Inc. Rahway, New Jersey 07065-0912 U.S.A.

Fold out label on plastic sleeve of Pioneer product

IVERMECTIN



Chewable Wormer

Ivermectin 22.7 mg/chewable

Anthelmintic and Boticide

Removes worms and bots with a single dose.
Contents will treat up to 1250 lb body weight
One chewable for each 250 pounds body weight

For Oral Use in Horses Only

5 Chewables per package

Equi Aid Products, Inc.
Phoenix, AZ

EQUI AID PRODUCTS, INC.

IVEKMECTIN

Chewable Wormer

For Oral use in Horses only Ivermectin 22.7 mg/chewable

Contents will treat up to 1250 lb body weight
One chewable for each 250 lb body weight

Anthelmintic and Boticide

For treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-Mouth Stomach Worms, Bots, Lungworms, Intestinal Threadworms, and Summer Sores. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

WARNING: DO NOT USE IN HORSES INTENDED FOR FOOD PURPOSES

CAUTION: Refrain from smoking or eating when handling. Wash hands after use. Avoid contact with eyes.
Keep this and all drugs out of the reach of children.

5 Chewables per package

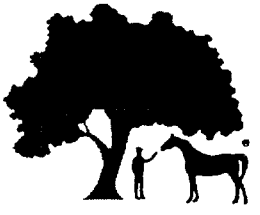
Lot #

Exp. Date

EQUI AID PRODUCTS, INC.

Bar Code

IVERMECTIN



Chewable Wormer

Ivermectin 22.7 mg/chewable

Anthelmintic and Boticide

Removes worms and bots with a single dose.
Contents will treat up to 1250 lb body weight
One chewable for each 250 pounds body weight

For Oral Use in Horses Only

5 Chewables per package

Equi Aid Products, Inc.
Phoenix, AZ

INDICATIONS Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.
Ivermectin Chewable Wormer provides effective control of the following parasites in horses.
Large Strongyles (adults) *Strongylus vulgaris*, (also early forms in blood vessels), *S. endentatus* (also tissue stages), *S. equinus;*
Small Strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., (adult) *Triodontophorus* spp.;
Pinworms (adult and fourth stage larvae) *Oxyuris equi*;
Ascarids (adults and third- and fourth-stage larvae) *Parascaris equorum*;
Hairworms (adult) *Trichostongylus axei*;
Large Mouth Stomach Worms (adults) *Habronema muscae*;
Bots (oral and gastric stages) *Gastrophilus* spp.;
Lungworms (adults and fourth stage larvae) *Dictyocaulus arnfieldi*;
Intestinal Threadworms (adults) *Strongyloides westeri*;
Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae;
Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: This package (all 5 chewables) contains sufficient Ivermectin Chewable Wormer to treat one 1250 pound horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each chewable contains enough ivermectin (22.7 mg) to treat 250 lb body weight. Hand feed as a treat, administer as a top-dress on feed or mix with the horses daily grain ration.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment should be repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Ivermectin Chewable Wormer effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *Strongylus vulgaris*.

Front of BOX

PRODUCT ADVANTAGES: ***Broad-spectrum Control*** Ivermectin Chewable Wormer kills important internal parasites, including bots and the arterial stages of *Strongylus vulgaris*, with a single dose. Ivermectin Chewable Wormer is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate

SAFETY: Ivermectin Chewable Wormer may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility

WARNING: DO NOT USE IN HORSES INTENDED FOR FOOD PURPOSES

CAUTION: Ivermectin Chewable Wormer has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes ***Keep this and all drugs out of reach of children.***

Note to User: Swelling and itching reactions after treatment with Ivermectin Chewable Wormer has occurred in horses carrying heavy infestations of neck threadworm (Onchocera sp. microfilariae). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with Ivermectin Chewable Wormer. Reinfestation, and measures for its prevention, should be considered. Consult your veterinarian if the condition does not improve.

Each package contains 5 chewables

Lot No. & Exp. Date

BAR CODE

EQUI AID PRODUCTS, INC.®
Phoenix, AZ 85027

IVMT-BL-0G1